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PATENT
Attorney Docket No.: JHU1630-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Sukumar et al.	Art Unit:	1634
Serial No.:	10/059,579	Examiner	J. S. Sitton
Filed:	January 28, 2002	Confirmation No.:	7778
Title:	ABERRANTLY METHYLATED GENES AS MARKERS OF BREAST MALIGNANCY		

MAIL STOP AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF APPLICANTS UNDER 37 C.F.R. § 1.131

Sir:

We, Saraswati Sukumar, Ella Evron, William C. Dooley, Nicoletta Sacchi, Nancy Davidson, and Mary Jo Fackler, co-inventors of the above-identified patent application do hereby declare and state that:

We are co-inventors of the above-identified patent application, which was conceived and reduced to practice in the United States.

We are familiar with the contents of the above-identified patent application.

We have reviewed the Sirchia et al. reference (Oncogene (2000) 19:1556-1563) and are aware that it was published in 2000, which is more than one year prior to the January 28, 2002, filing date of the above-identified patent application.

We are also aware that the Examiner has asserted that the Sirchia et al. reference allegedly anticipates the claims of the above-identified patent application under 35 U.S.C. § 102.

It is respectfully submitted that the claimed invention was conceived in the United States and reduced to practice prior to the 2000 publication date of the Sirchia et al. reference, as supported by the evidence which follows:

At the time the present invention was conceived and reduced to actual practice, we were members of the research team that performed the experiments set forth in the Examples of the present application and in U.S. application Serial No. 09/771,357, filed January 26, 2001, from which application the present invention claims priority under 35 U.S.C. §120. These experiments were completed in laboratories of The Johns Hopkins University School of Medicine in Baltimore, Maryland prior to the publication date of the Sirchia et al. reference.

At the time the present invention was conceived and reduced to practice, Nicoletta Sacchi was the leader of the research team that authored the Sirchia et al. article, and Saraswati Sukumar was one of the co-authors of the Sirchia et al. reference. The research described in the Sirchia et al. reference was conceived by the co-inventors of the priority application and was carried out under their direction.

Nicoletta Sacchi and Saraswati Sukumar, who are named as co-authors of the Sirchia et al. reference, are both co-inventors of the present application and contributed to conception of the invention described in the priority application. By contrast, Silvia M. Sirchia, Anne T. Ferguson, Elena Sironi, Smitha Subramanyan and Rosaria Orlandi, who are named as co-authors of the Sirchia et al. reference, contributed to the research effort that led to the Sirchia reference, but did not contribute to conception of the invention as described in the present application or as described in the priority application.

Thus, we maintain that the subject matter contained in the Sirchia et al. reference that is relied upon in the rejection of claims 1-2, 4, 6-9 11-20, 22-31 and 34-41 of the present application for alleged anticipation was conceived and reduced to practice by the

co-inventors of the present application prior to the date of publication of the Sirchia et al. reference. Further, we, the co-inventors, were diligent from the time of conception of the invention until the time of filing the above-identified priority application.

4. We further declare that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

S. Sukumar
Date

Date

Date

Date

2/10/04
Date

2/10/04
Date

S. Sukumar
Saraswati Sukumar

Ella Evron

William C. Dooley

Nicoletta Sacchi

N. Davidson
Nancy Davidson

Mary Jo Fackler
Mary Jo Fackler

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Ella Evron

William C. Dooley

Nicola Sarchi

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Mary Jo Raeler

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William C. Dooley
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